REMARKS/ARGUMENTS

Claims 1, 5-7, 9, 11-14, 16-19 and 105-113 are active in this case.

Support for Claims 113 is found in Claim 1 and on page 35, lines 1-6.

No new matter is added.

Applicants disagree with the rejection of Claims 1, 9, 18 and 106-108 under 35 USC 102(b) in view of Heard because again Heard does not explicitly describe treating traumatic brain injury (TBI) but certain types of infections nor does Heard inherently describe treating patients suffering from TBI.

Further, with respect to Claim 113, Heard does not describe identifying TBI suffering mammals and then treating those suffering mammals.

As acknowledged and discussed on pages 34-35 of the present application, Heard merely presents a study on the use of GCSF for the prophylactic treatment of "nosocomial infections in intubated patients with acute TBI **or** intracerebral hemorrhage" (pp. 749, 1st col. 2nd ¶, empahasis added) but does not describe treating TBI in the patients.

One of the reasons the rejection has been maintained as explained on page 5 of the Action is "in so far as the Heard reference describes administration of Filgrastim to even one TBI patient, it fully anticipates the method of the claims." This may be true if Heard actually taught that a TBI intubated patient received the drug but Heard actually does not do that. Accordingly, Applicants respectfully disagree with the basis for the rejection and respectfully submit that the rejection is not based on the proper application of the law as it relates to inherent anticipation.

On page 749, col. 1 under the heading "Materials and Methods," Heard describes the study as a "randomized, placebo-controlled, double-blind multicenter study." As is well-known in the field of clinical trials, such studies are conducted under the situation where the

study coordinators know nothing about the patients, healthy or sick, drug or placebo, or what type of illness an individual patient suffers from. The focus of the patients is the infections arising from intubated patients, the patients with acute TBI **OR** intracerbral hemmorage. Thus, what Heard describes is that some of the patients enrolled in the study may have had TBI, and it is **possible** that all of the patients who were treated with the test drug (as opposed to placebo) could have been intubated patients with intracebral hemmorage. While it is possible that one intubated patient may have been one with acute TBI and that one patient may have received the drug in question, the mere possibility that something may have happened to a patient is not a sufficient basis to reject a claim based on inherent anticipation. The law requires that "Inherency. . .may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991) (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). As the basis of the rejection (because that's what Heard describes) is that an intubated TBI patient may have received the drug in question, the rejection cannot be maintained.

Thus, it is clear that Heard does not suggest to treat TBI or cerebral hemorrhage but, at best, a side effect of the intubation which is sometimes performed during TBI or cerebral hemorrhage. Furthermore, as the result of the study described in Heard, it is not suggested to treat patients with TBI or cerebral hemorrhage with G-CSF in order to prevent nocosomial infections. Rather, Heard makes clear that G-CSF had no effect with respect to pneumonia or urinary tract infection (see paragraph 4 of the Discussion). G-CSF had no effects on mortality or length of stay (see last passage of the abstract). Even with respect to bacteremia, where somehow an effect was observed, Heard does not suggest to treat patient with G-CSF but only recommends a further study (see the last two paragraphs of the Discussion).

Consequently, Heard does not suggest to treat TBI patients or patients with cerebral hemorrhage with C-CSF in order to prevent nocosomial infections.

Another reason that the rejection was maintained, as explained on page 5 of the Action, is that "the claims neither call for a specific feature by which to limit the patient pool of TBI patients, nor do the claims stipulate specific criteria by which "treatment" of TBI is assessed." With respect to point (1), Claim 1 has been amended to define that the mammals being treated are those suffering from TBI. That is, the claims target those mammalian patients in need of treatment for TBI. With respect to point (2), Claim 113 defines that as a first step, the mammalian patient be identified as having TBI then after having so identified that patient, the patient is administered the compound(s) as defined in the claims.

Heard does not present a beneficial effect on the TBI symptoms nor even discuss such an effect. All of the targeted patients of this study were intubated but not necessarily due to a prior TBI. Therefore, Heard does not describe or even suggest that a patient suffering from TBI be targeted as in the claimed method (Claim 1) nor that one would identify a patient suffering from TBI so that patient can subsequently receive the administrated compound(s).

To the obviousness rejections citing primarily Heard with Brines, Deleuze, Morita-Fujimura, Curran and Goa, MacVitte and/or the Neupogen® publication (new rejection), these rejections also fail because they are relied upon for features in various dependent claims or for intravenous administration (see Neupogen® combined with Heard) but these secondary publications do not (A) explicitly describe treating a mammal suffering from traumatic brain injury (TBI); and (B) inherently describe treating a mammal suffering from TBI. Further, Heard would not have been modified to treat the underlying condition of TBI because Heard is silent about such effects.

Withdrawal of the rejections under 35 USC 103 is requested.

The rejection under 35 USC 112, second paragraph is traversed.

The term hemodynamic active is neither novel nor indefinite. Indeed, hemodynamic is a well-known term in the field and generally deals with controlling the circulation of blood through the body (see, e.g., attached print out from the International Hemodynamic Society, www.hemodynamicsociety.org). Whether a compound does this or not can easily be ascertained by one in the field. Thus, Claim 11 sets out and circumscribes a particular subject matter with a reasonable degree of clarity and particularity.

In Claim 13, the term facilitates has been modified so as to clarify what is being claimed. That is the agent "facilitates" passage of the GCSF or its derivatives as now defined in Claim 13 to pass through the blood-brain barrier. The term facilitates is a well-defined term, e.g., as defined by dictionary.com it is "to make easier or less difficult; help forward (an action, a process, etc.)" Thus, the agent here makes it easier or less difficult for GCSF to pass through the blood brain barrier, a notoriously well-known barrier for directed therapy in the brain.

Withdrawal of the rejection is requested.

To the provisional obviousness double patenting rejection in view of claims 1-5, 9-22 and 52-53 of co-pending application no. 10/880,101.

The claims here are for treating traumatic brain injury (TBI) whereas the pending claims of the 10/880,101 are for treating peripheral neuropathy. Treating one condition does not necessarily result in treating the other condition and vice versa nor would it be obvious to do so. That the specification of the '101 application states that peripheral neuropathy can be caused by a primary lesion or dysfunction of the nervous system does not mean that treating

TBI is an obvious variant of treating peripheral neuropathy (and vice versa) because they are different conditions, each with their own unique pathologies.

Withdrawal of the rejection is requested.

A Notice of Allowance is also requested.

Respectfully submitted,

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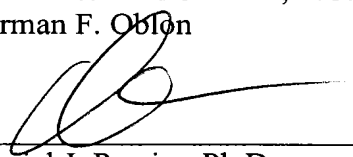

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